K102671

Siemens Medical Solutions USA, Inc.
Oncology Care Systems

Section 5

OCT 1 8 2010

510(k) Summary

Date Prepared: September 09, 2010

Submitter: Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
Concord, CA 94520

Contact: Christine Dunbar
Senior Regulatory Affairs Specialist

Phone: (925)602-8157
Fax: (925)602-8008
Email: christine.dunbar@siemens.com

Proprietary Name: *syngo*® RT Therapist Connect Workspace, v4.2

Common Name: Accessory To; Medical Charged-Particle Radiation Therapy System

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

Product	510(k) Clearance / Date	Claim of Equivalence for:
syngo® RT Therapist Connect Workspace with RT Therapist version VA20	K090683 / May 08, 2009	syngo® RT Therapist Connect Workspace, for RT Therapist with Software update VB10 (RTTC v4.2)
ARTISTE™ Solution (aka ARTISTE MV) with Control Console 11.0	K072485 / Dec. 27, 2007	syngo® RT Therapist Connect Workspace for RT Therapist with Software update VB10 (RTTC v4.2) and Control Console 12
ONCOR™ Expression with Control Console 9.0	K060226 / Mar. 15, 2006	syngo® RT Therapist Connect Workspace for RT Therapist with Software update VB10 (RTTC v4.2) and Control Console 12

The update to the *syngo*® RT Therapist Connect Workspace, v4.2 as described in this premarket notification has the same intended use and fundamental scientific technical characteristics as the predicate devices listed above.

Description Summary

syngo® RT Therapist Connect Workspace, v4.2:

Technological Characteristics:

The *syngo*® RT Therapist Connect Workspace v4.2 release is intend to update customers with the *syngo*® RT Therapist Connect Workspace with versions v4.1 (ARTISTE systems) and v2.1a (ONCOR / PRIMUS systems). The technological characteristics of the *syngo*® RT Therapist Connect Workspace v4.2 remain unchanged from the currently cleared product.

The *syngo*® Software Architecture:

The *syngo*® RT Therapist Connect software utilizes the proprietary *syngo*® software architecture design provides a method of delivering customized software applications based on the modality as clinically supporting packages. From these applications SIEMENS utilizes, as part of the Oncology clinical focus package, multiple applications for patient set-up and position verification, treatment localization, treatment verification, portal imaging as well as data processing, image reformatting, display and printing. The currently cleared COHERENCE™ and *syngo*® products also include an array of image-oriented software tools, support for DICOM connectivity and Siemens Remote Service.

Refer to Section 11- Design Description, for the Product and Sub-System Requirements Specifications regarding these specific requirements.

General Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Intended Use:

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

<u>The *syngo*® Suite for Oncology Workspaces:</u>

The *syngo*® workspaces includes a number of *syngo*® based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The

workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

The *syngo*® RT Therapist Connect Workspace v4.2, is an additional option when third party OIS, Treatment Planning Systems and/or PACS devices are intended to be used in conjunction with the Siemens branded Linear Accelerator system. The *syngo*® RT Therapist Connect Workspace v4.2, is a software application that permits patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording. The *syngo*® RT Therapist Connect Workspace v4.2, can be interfaced with third party OIS, TPS and other validated devices conforming to the DICOM Standard.

Substantial Equivalence:

The Substantial Equivalence comparison chart in Section 12 demonstrates the comparison of the technological characteristics of the *syngo*® RT Therapist Connect Workspace v4.2 and Control Console 12 update to the currently cleared predicate devices.

The *syngo*® RT Therapist Connect Workspace v4.2, does not change the intended use of the original *syngo*® RT Therapist Connect Workspace or the Siemens branded Linear Accelerator Systems.

Bench Testing:

Bench testing in the form of Unit, Integration and System Integration testing was performed to evaluate the performance and functionality of the software update for the RT Therapist Connect and the Control Console, version 12. All testable requirements in the Software Requirements Specifications (SRS), Sub-System Requirements Specifications (SSRS), and specifically, the Functional Specifications (FS) for the Control Console software and Function Controller firmware, have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process (PDP).

The software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Plans.

Non-Clinical Test Results:

Validation of the *syngo*® RT Therapist Connect Workspace, v4.2 and Control Console 12 has been performed at the System test level on production prototype devices by appropriately trained and knowledgeable test personnel. System level validation and regression testing has been performed successfully, demonstrating that the software meets the acceptance criteria as noted in the system test plans.

Testing to Consensus Standards:

The *syngo*® RT Therapist Connect Workspace, v4.2, Control Console and firmware have been tested to meet the requirements for conformity (where applicable) to the following standards:

- IEC 60601-1-4:1996+ A1: 1999 – Medical Electrical Equipment: Part 1-4: General requirements for Collateral Standard: Programmable Electrical Medical Systems
- IEC 62304:2006 Medical Device Software – Software Life Cycle Processes

Substantial Equivalence to Predicates:

The verification testing to the software and component requirements (Control Console), validation of the intended use, and the regression testing to the existing RT Therapist Connect software and Control Console functional requirements, is intended to support the claim of substantial equivalence to the currently cleared *syngo*® RT Therapist Connect Workspace, v4.1 and v2.1a. (K090683), the currently cleared Control Consoles and Function controllers for the ARTISTE (K072485) and ONCOR (K060226) medical linear accelerators.

Summary:

In summary, it is SIEMENS' belief that the *syngo*® RT Therapist Connect Workspace v4.2 update and the Control Console version 12 do not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Christine Dunbar
Senior Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
4040 Nelson Avenue
CONCORD CA 94520

Re: K102671
Trade Name: syngo® RT Therapist Connect Workspace, v4.2
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 09, 2010
Received: September 16, 2010

OCT 12 2010

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

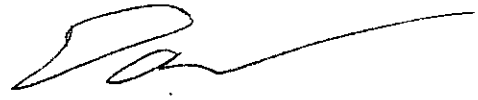
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4

Indication For Use Statement

510(k) Number (if known): K102671

Device Name: syngo® RT Therapist Connect Workspace, v4.2

Indications for Use:

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The *syngo*® Suite for Oncology Workspaces:

The *syngo*® workspaces includes a number of *syngo*® based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

The *syngo*® RT Therapist Connect Workspace, v4.2, is an additional option when third party OIS, Treatment Planning Systems and/or PACS devices are intended to be used in conjunction with the Siemens branded Linear Accelerator system. The *syngo*® RT Therapist Connect Workspace, v4.2 is a software application that permits patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording. The *syngo*® RT Therapist Connect Workspace can be interfaced with third party devices conforming to the DICOM Standard.

The addition of the *syngo*® RT Therapist Connect Workspace, v4.2, does not change the intended use of the Siemens branded Linear Accelerator System.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

K102671